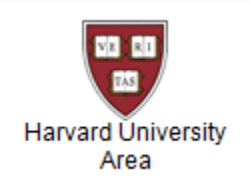

HUA IRB Monthly Newsletter

To get you up-to-speed on recent events in the HUA IRB office as well as in the IRB world

New NIH Data Sharing Policy

"To promote the management and sharing of scientific data generated from NIH-funded or conducted research", the National Institutes of Health (NIH) recently published a comprehensive data sharing policy that will take effect January 25, 2023, by which researchers must submit a plan on what they will share, how it will be shared, as well as how long it will be shared. This policy will pertain to new NIH funding as well as competing funding. You can learn more on the NIH website here -

Proposed Revisions to the NIH Genomic Data Sharing Policy

To stay current with changes in technology and as data sharing is "widely recognized as a best practice for advancing research and the promise of societal benefit continues to evolve", the NIH is seeking input on proposed changes to the 2014 Genomic Data Sharing Policy. To see the proposed changes and comment (should you wish), please visit the NIH website here - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-029.html

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

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URTP Training Dates

Upcoming training dates for the Undergraduate Research Training Program (URTP) have now been posted. The URTP Training provides an opportunity to learn about what types of research require IRB review, best practices for conducting ethical research, an overview of human subject protections, and additional resources that may be helpful to the student researcher.

The in-person training sessions are an alternative to the standard online CITI training. The sessions have been developed with students in mind: they are 90 minutes in length, interactive, and developed with enthusiasm and energy.

All Spring 2022 “in-person” sessions will be held by Zoom. Follow the links below to the Harvard Training Portal to sign up for a session. Sign-up will close one business day before the session and a Zoom link will be sent by email to all confirmed attendees at that time.

Date: March 9, 2022 (Wednesday)
Time: 4-5:30pm
Location: Zoom (link to follow)
Please sign up for the March 9th training by clicking here!

Date: March 22, 2022 (Tuesday)
Time: 5-6:30pm
Location: Zoom (link to follow)

Please sign up for the March 22nd training by clicking here!

Date: March 31, 2022 (Thursday)
Time: 4:30-6pm
Location: Zoom (link to follow)
Please sign up for the March 31st training by clicking here!

Date: April 11, 2022 (Monday)
Time: 4:30-6pm
Location: Zoom (link to follow)
Please sign up for the April 11th training by clicking here!

Do You Speak IRB?

Does an Oral History Project Require IRB Review?

There are many types of research that require IRB review as well as many types that don't. The HUA IRB (and all other IRBs) use the term "regulated research" to differentiate the types of research that are "regulated" and require IRB review. So, what **is** regulated research?

The federal regulations that govern human subjects research define research that requires IRB review as:

"…a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." 45 CFR 46.102(l)

Many of the "not research" determinations that the HUA IRB makes are because the research activity is not designed/intended to be "generalizable". But what does "generalizable" mean?

Generalizable knowledge is information that is expected to expand the knowledge base of a scientific discipline or other scholarly fields of study and yield one or both of the following:

- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Now, let's get back to oral history research. Most oral history research does not require IRB review because the intent of the activity is limited to only documenting or reporting on events, situations, policies, institutions, or systems without the intent to form hypotheses, draw conclusions, or generalize findings. It will **not** involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices. Oral history is telling the story of individuals. As such, most oral history projects do not require IRB review because it is not "regulated research"; the activity is not "designed to develop or contribute to generalizable knowledge".

There has been so much conversation about whether oral history requires IRB review that the revised federal regulations included a “shout-out” that most oral history does not require IRB oversight by including it as an example of what is not considered research (*45 CFR 46.102(l)*):

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

According to our federal regulators, “This category of activities was removed from the regulatory definition of "research" to resolve longstanding debate and uncertainty in the research community regarding whether these activities are considered research for the purposes of regulatory oversight.”

Here is an example of what WOULD NOT require IRB oversight:

The creation of a video of interviews with war survivors. The sole purpose is to create a historical record of personal events and experiences related to the Gulf War.

What about those oral history projects that do require IRB review – how are they different?

When an oral history project focuses on something bigger than the individual or group and will form a hypothesis or draw a broad conclusion, then the activity is headed to being regulated research.
According to OHRP, “It is not the field that removes the activity from the definition, but rather that the purpose and design of the activity are to focus on specific individuals and not to extend the activity’s findings to other individuals or groups.”

Here is an example of what WOULD require IRB oversight:

Qualitative interviews of war veterans to document their experiences and to demonstrate the need for additional research and facilities for the treatment of traumatic brain injuries.

Of course, if there is any question about whether your study requires IRB oversight, please contact the HUA IRB at any time – cuhs@harvard.edu

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Here is where you can find us:
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